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# Biotechnology Notes

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**Biotechnology Notes**, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

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## INSIDE USDA

### APHIS: KEEPING PACE WITH BIOTECHNOLOGY

The Animal and Plant Health Inspection Service (APHIS) began issuing permits for biotech products in July 1987. Now, almost two years and more than 500 permits later, APHIS is pleased to say that each of those applications for a permit was reviewed within the mandatory deadlines spelled out in the regulations.

Terry Medley, Director of the Biotechnology, Biologics, and Environmental Protection (BBEP) unit at APHIS, attributes much of the success of the biotech regulatory program to cooperation from both the regulated community and the BBEP staff. "We started off with just myself, a program analyst, and any technical staff I could borrow," said Medley. "But it soon became clear we needed to consolidate related staffs to help process the influx of applications, analyze scientific data, and prepare environmental assessments."

Today, more than 100 people work in BBEP, including biotechnologists, molecular biologists, molecular geneticists, environmental ecologists, and animal and plant physiologists. Medley said he will need to continuously add to the staff just to "keep pace" with the number of new products that will soon be ready for field tests.

As for the long-term, Medley sees the industry moving from small-scale to large-scale field testing. Although he doesn't see the need for new legislation, he believes the current regulations may need to be amended to reflect different molecular techniques. "It really isn't a problem for us as regulators," he says, "because when we wrote the regulations we built into them the flexibility to change as the technology advanced."

He said he also thinks that over time more organisms will be exempted from certain regulatory requirements. "The increase in our knowledge about what organisms can and can't do in the environment is expanding rapidly," he said. "Since the regulations are science-grounded, they must reflect these new knowledge bases in order to remain viable."



## AG GOES BACK TO SCHOOL?

Project Interact is a USDA-sponsored program designed to revitalize colleges of agriculture so that graduates may be better prepared to meet society's social, economic, technological, and agricultural challenges.

At Project Interact's first meeting last March, the executive-advisory committee, comprised of 20 representatives from academia, government, and business, emphasized the need for colleges of agriculture to re-define their mission in terms of society's needs so that graduates may enter the business community or pursue the humanities as well as compete for careers in agriculture. Specifically, the committee identified a number of areas that need improvement: curriculum design, quality of instructional materials, faculty development programs, more experiential learning courses, and multidisciplinary approaches to teaching. A final report that will include recommendations will be presented at a national conference sometime in 1990. To learn more about Project Interact, call Jane Coulter at USDA's Office of Higher Education on (202) 447-7854.

## OAB TO BRIEF CANADIANS

The Office of Agricultural Biotechnology (OAB) will meet with representatives of Environment Canada this month to discuss USDA's draft research guidelines. They will also learn about the Cooperative State Research Service's National Biological Impact Assessment Program (NBIAP). The NBIAP is collaborating with the research community on a computerized information data base that facilitates safe field testing of genetically modified organisms.

Environment Canada, an organization similar in mission to that of the U.S. Environmental Protection Agency (EPA), is now in the process of developing regulations for outdoor field trials. During a visit to USDA last month, the Canadians met with officials from APHIS and were briefed on the Department's regulatory framework.

## ALVIN YOUNG SELECTED OAB DIRECTOR

On June 1 Alvin L. Young became permanent OAB director, after serving in that position on a temporary detail for 18 months. An internationally recognized scientist, author, and lecturer, Young came to USDA after four years as a senior policy analyst for life sciences in the Office of Science and Technology Policy, an office of the Executive Office of the President. A native of Laramie, Wyoming, Young has served in various research, academic, and policy positions with different Federal agencies, including six years as associate professor of biological sciences at the U.S. Air Force Academy and later as a special assistant to the Air Force on environmental issues. For three years he was Director of Research for Environmental Issues with the Veterans Administration. He has done extensive research on dioxins and written or co-authored four books and 120 scientific articles on environmental issues. In addition to his new position as OAB Director, Young is also Executive Secretary of the Department's Agricultural Biotechnology Research Advisory Committee (ABRAC), as well as the Secretary's science advisor. Young retired May 31, 1989 as a Colonel from the U.S. Air Force.

## AGENCIES UPDATED ON RESEARCH GUIDELINES

The OAB staff visited APHIS and EPA on June 6 to brief senior officials on the status of the draft research guidelines and to gain feedback on the scope of the guidelines. APHIS officials suggested the text focus more on principles for safe field testing rather than laying out specific criteria for researchers to follow. EPA offered ideas for fine-tuning a table of examples of unmodified organisms. OAB is now reviewing comments submitted by the National Institutes of Health and the Food and Drug Administration. A preamble is also being prepared as well as an environmental impact statement. The guidelines should be ready for publication in the Federal Register later this summer.

## NEWS AROUND THE COUNTRY (AND THE WORLD)

### INSECTS "TURN ON" PLANT GENES

Some of nature's best kept secrets lie in the role of genes. The ones that react to environmental stresses, such as drought, insects, or diseases, are particularly important to the researcher because of their influence on agricultural production. Now, as a result of a field trial conducted last summer in Ames, Iowa, scientists know more about those plant genes that "turn on" insects and how plants and insects interact.

Robert Thornberg and Lisa Molin, Iowa State University researchers, used the tobacco plant as a model for their field trial, which was conducted under a permit issued by APHIS in the spring of 1988. The plants contained a wound-inducible gene designed to turn on when attacked by insects. Several kinds of beetles chewed on the leaves. Large areas of plant leaves were also consumed by the tobacco hornworm larvae. In addition, in one corner of the field, dense populations of aphids covered plant leaves and stems.

The wound-inducible gene turned on only in those plants that were gnawed and chewed by insects. The aphids did not trigger the special gene, indicating the aphid attack was not as significant as the other wounds.

Through biotechnology, more is being learned about the relationship between plants and the elements. In the case of research projects like this one, it is hoped that genetic manipulation may provide a means of conferring resistance to insects and provide an alternative to the use of chemical sprays.

### U.S. DRAFTS INTERNATIONAL BIOTECH GUIDELINES

An initial paper on good developmental practices was drafted by the U.S. delegation at the meeting of the Organization for Economic Cooperation and Development (OECD) held June 13-16 in Paris, France. APHIS played a major role in drafting the paper, which describes guidelines for conducting low-risk field trials. The document was favorably accepted by the OECD, which has 23 member countries that represent industrialized nations around the world. Three USDA people -- Terry Medley, Sue Tolin, and Sally McCammon -- were part of the U.S. delegation.



## VOX POPULI: THE VOICE OF THE PEOPLE

Initial results of an opinion poll on biotechnology conducted on North Carolinians show most people (77%) feel that producing more nutritious food is the most desirable use of genetic engineering. Eighty percent of those surveyed said too little regulation of genetic engineering poses serious risks to human health, and two-thirds said genetic engineering will give large-scale farmers an unfair advantage over small-scale farmers. Seventy-five percent said North Carolina should have its own regulations in addition to Federal regulations. These are a few of the numbers reported in the spring issue of Techne, a publication of the North Carolina Biotechnology Center.

The poll was sponsored by the Center and conducted by telephone, mail survey, and through personal interviews. Rural farmers, rural non-farmers, urban residents and agricultural leaders from industry, state government, the extension service and public interest groups responded to the questions.

Detailed results of the survey will not be available until this fall after all of the data has been compiled and interpreted. To subscribe to Techne, call (919) 541-9366.

## BIOTECH REGULATIONS UNDER REVIEW

How the Federal government regulates biotechnology products is the focus of a study now being conducted by the Administrative Conference of the United States, an independent Federal agency established in 1964 that identifies administrative law issues and problems. Its recommendations for improvement are sent to the President, the agencies, the Congress, and the courts.

The study is examining Federal coordination of biotechnology regulation at EPA, USDA, and the Food and Drug Administration. The role of the Office of Science and Technology Policy is also being reviewed as well as the adequacy of risk assessment, management techniques, and methods of informing the public. A final draft should be ready this fall.

Members of the Administrative Conference are appointed by the President and come from both the public and private sectors.

## RESEARCH TO BEGIN ON AIDS-LIKE VIRUS IN CATTLE

Three Iowa State University researchers and three researchers with USDA's Agricultural Research Service National Animal Disease Center will investigate the bovine immunodeficiency virus (BIV) as a potential model for the study of AIDS in humans. Both BIV and human immunodeficiency virus, which causes AIDS in humans, are retroviruses and are similarly structured.

Learning what BIV does to the immune system of cattle, the biology of the virus, how it replicates, and how the immune system helps control the virus may lead to a better understanding of the AIDS virus. The grant for the 5-year investigation was awarded by the National Institute's of Health National Cancer Institute.

- USDA and the Joyce Foundation helped to support a conference May 22-24 in Ames, Iowa on "Biotechnology and Sustainable Agriculture: Policy Alternatives." Some of the points brought out at the workshop on herbicide resistance were the need for more information on the impact of technology on the environment and the need for more research on alternative practices. Those attending the biopesticides workshop said there is a need for a depository of microbial resources as well as more research on microbial ecology and public input. Ideas brought out at the animal growth promotants workshop included a desire for a research advisory group, more public education programs, and thoughts to labeling biotech products for the consumer. The disease control in animals group said there was a need for improved animal disease surveillance, more information on the effect of biotechnology on small, medium and large scale production systems; more research on animal welfare measurement; and more information and education programs. Proceedings of the conference will be available in March 1990.
- The Experiment Station Committee on Organization and Policy (ESCOP) and the Cooperative State Research Service sponsored a symposium, "Meeting the Challenge of the 1990's," June 13-15. Among the topics covered were the 1990 farm bill, U.S. agriculture in world markets, water quality issues, the use of pesticides, diet and health issues, the impact of technology on the economy, technology transfer, and science policy initiatives. Robert Grady from the Office of Management and Budget said the major thrust in agricultural research policy is in the areas of environmental protection, biotechnology, international competitiveness, and recruitment and training at 1890 institutions.

OAB Director Alvin Young spoke on "Who Will Reap the Rewards of Biotechnology?" He said the general public, the nation, and the world stand to benefit from advances in agricultural biotechnology. He emphasized the importance of reaching out to the public to gain its understanding and support for biotechnology and the need to "harmonize" standards for public safety and environmental protection.

Kenneth Kay, an attorney with the Council on Research and Technology said to be ware of "research oversell" which might affect the credibility of the research community. He said goals have not been set for technology transfer programs and as a result it will be difficult to evaluate these programs. Management of the technology is as important as the technology itself, said Kay, and the Federal role in technology transfer will be smaller as state and local governments take on more responsibility.

- A working group of the ABRAC met June 22-23 to discuss the table of examples in the draft research guidelines and other related issues. The committee used a scientifically based schematic to identify 10 characteristics of organisms. These traits are then used to develop a 5-step process which assigns a safety condition to the unmodified organism. The Working Group's recommendations will be incorporated into the research guidelines, which will be sent to all of the ABRAC members by mid-July for final review.
- "Federal-State Regulation of Biotechnology: Plants and Microorganisms" was the topic of a conference held in Research Triangle Park, N.C., June 25-28. Sponsored



by APHIS, the meeting provided a forum for the exchange of information on the current status of Federal and state regulation of biotechnology. Panelists included representatives from USDA, the Food and Drug Administration, EPA, State departments of agriculture, academic institutions, the biotechnology industry, and environmental organizations. Sue Tolin, a member of USDA's ABRAC, gave an overview of the draft research guidelines. More than 25 states from all geographical regions, Puerto Rico, and U.S. territories and possessions attended the conference. Highlights from the conference and a summary of the critical issues raised by states in a national survey conducted by APHIS will be made available to those states considering proposing biotechnology legislation.

#### NEW PUBLICATIONS

Two new easy-to-read publications are now available from the Industrial Biotechnology Association: "Agriculture and the New Biology" and "Food for the Future." Up to 10 copies are free of charge; 11-100 are \$.50 each; more than 100 copies, \$.40 each. To place an order, call the Association at (202) 857-0244.

"Biotechnology: Economic and Wider Impact." Prepared by the Organization for Economic Cooperation and Development. \$20. To order, call (202) 785-6323.

"The Laws of Life: Another Development and the New Biotechnologies." A study prepared by the Dag Hammarskjold Foundation in Uppsala, Sweden. It focuses primarily on the impact of biotechnology on Third World Countries. Copies cost \$18 for individuals; \$33 for corporations. To order, call (919) 542-5292.

"First in the Field" is a 15-minute color videotape that chronicles Iowa State University's 1988 field test on tobacco. The tape includes discussion of biotechnology's potential for agriculture, the roles of state and Federal government in biotechnology research, regulation, and safety. Call Iowa State University at (515) 294-1540 for information on renting or purchasing the videotape.

"Farm Animals of the Future" is a two-part article appearing in the April and May 1989 issues of Agricultural Research, a magazine prepared by USDA's Agricultural Research Service. The article explains how biotechnology techniques may impact on the future health and productivity of poultry, swine, cattle, and sheep. A limited number of copies are available and may be obtained by calling the editorial office at (301) 344-3280.

Focus 1988 is the proceedings of a national symposium held in Washington, D.C. last year in honor of the first class of USDA national needs graduate fellows. Limited copies are available by calling USDA's Office of Higher Education at (202) 447-7854.

Minutes of the January 5-6 meeting of USDA's ABRAC are now available. Participants at that meeting discussed the draft research guidelines and a proposal submitted by Texas A&M University to evaluate in cattle a new brucellosis vaccine. Copies of the minutes are available by calling OAB at (202) 447-9165.



## UPCOMING MEETINGS

July 6-7: "Biotechnology in a Global Economy." Washington, D.C. Sponsored by the Office of Technology Assessment. Speakers from 16 foreign countries will present detailed reports on biotech developments in their countries. For more information, call Rand Snell at (202) 228-6670.

July 6-7: Meeting to explain licensing methods and procedures for companies marketing veterinary biologics. Ames, Iowa. Sponsored by APHIS. For more information, call David Espeseth at (301) 436-8245.

July 10-12: "Dealing with Field Test Regulations and Public Acceptance of Engineered Plants and Microbes." Baltimore, Md. Sponsored by the University of Maryland Biotechnology Institute and the Center for Public Issues in Biotechnology. Call (301) 455-3733.

July 17-21: Advanced Techniques in Food Biotechnology. Lisbon, Portugal. Write to V. Loureiro, Department of Microbiology, Instituto Superior de Agronomia, 1300 Lisbon, Portugal.

July 20: "Overview of Biotechnology Environmental Release Issues." Rockville, Md. Presentation given by Edward Korwek, a lawyer/scientist with the law firm of Hogan and Hartson, and a member of USDA's ABRAC. Sponsored by Montgomery County, Md's High Technology Council, Inc. Call (301) 762-6325 to make a reservation.

July 26-28: Cotton Biotechnology Workshop. Sponsored by the National Cotton Council and the Joint Cotton Breeding Policy Committee. Dallas/Ft. Worth, Texas Marriott Hotel. Call Jim Brown at (901) 274-9030.

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